

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

IN RE: **KUMAR, Vijay et al.**)
) APPEAL NO. _____
SERIAL NO: 10/007,866)
)
FOR: BIODEGRADABLE OXIDIZED)
 CELLULOSE ESTERS)
) BRIEF ON APPEAL
FILED: December 6, 2001)
)
GROUP ART UNIT: 1623)

To the Commissioner of Patents and Trademarks
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Dear Sirs:

Please enter the following Brief on Appeal into the record.

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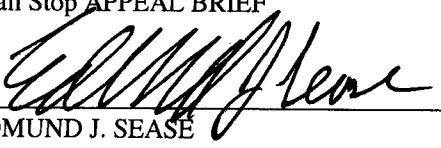

EDMUND J. SEASE

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I. INTRODUCTION

This is an Appeal of the re-opened prosecution Rejection dated October 2, 2008, rejecting claim 36. The appealed claim 36 is set forth in an attached Appendix.

II. REAL PARTY IN INTEREST

This application has been assigned to University of Iowa Research Foundation, an Iowa corporation, having an address of 1000 Oakdale Campus #214 TIC, Iowa City, Iowa 52242-5000. The Assignment was recorded at reel 012649, frame 0036 on February 27, 2002.

III. RELATED APPEALS AND INTERFERENCES

Appellant is aware of a pending appeal in application, Serial No. 10/975,248, which is a continuation-in-part of the present application. No decision has yet been rendered in this related appeal. The notice of appeal was filed in this other application March 31, 2008.

IV. STATUS OF CLAIMS

Claims 1-35 were originally submitted in the application dated December 6, 2001. In response to an office action dated July 24, 2003, Appellant canceled claims 1-6, amended claims 7-11, 13, and 16, and added claims 36-37. In response to a final office action dated March 9, 2004, Appellant filed a Request for Continued Examination (RCE) requesting entry of an amendment after final rejection withdrawing claims 13-34, canceling claim 37, and amending claims 7-12 and 35-36. In response to an office action dated March 25, 2005, Appellant withdrew claims 13-21 and 23-34, canceled claim 35, amended claim 36, and added claim 38.

In response to a final rejection dated November 1, 2005, Appellant filed a notice of appeal on December 13, 2005, appealing the rejection of claim 36, and subsequently filed its appeal brief on February 13, 2006. On May 16, 2006, in the Examiner's Answer to Appeal Brief, the Examiner withdrew the rejection of claim 36 under 35 U.S.C. § 102(b) in view of

the amendment to the claim filed August 25, 2005. In a decision dated February 28, 2007, the Board affirmed the rejection of claim 36 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement.

On April 27, 2007, Appellant filed a response along with a Request for Continued Examination (RCE). In response to a non-final action dated July 16, 2007, Appellant amended the specification and claim 36 to delete the subject matter that was the subject of the Examiner's rejection dated 35 U.S.C. § 112, first paragraph. In an office action dated December 21, 2007, the Examiner finally rejected claim 36 under 35 U.S.C. § 102(b). In response, Appellant filed a Notice of Appeal dated April 21, 2008 and a brief dated June 23, 2008. In an Action of October 2, 2008, the Examiner re-opened prosecution giving a different anticipation rejection than the previously appealed and briefed Final Rejection. This Appeal then followed. The claim here appealed is claim 36, as set forth in an attached Appendix.

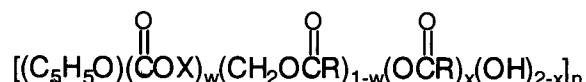
V. STATUS OF AMENDMENTS

No amendments were filed in Response to the re-opened prosecution Rejection dated October 2, 2008. A Notice of Appeal was timely filed on December 18, 2008.

VI. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 36 relates to a biodegradable, oxidized cellulose ester of either general formula I or II:

I.

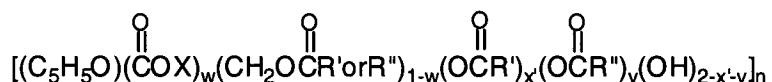


wherein:

X is selected from the group consisting of H, Na, K, Ca, NH₄, and NEt₃H;
whereby R is (CH₂)_nCOOH, where n is 2 to 4;
w is 0.1-1.0;
x is 0.1-2.0; and
n is 30-1500.

and

II.



wherein:

X is selected from the group consisting of H, Na, K, Ca, NH₄, and NEt₃H;
R' and R'' are each selected from the group consisting of: H; CF₃; (CH₂)_nCH₃, where n is from 0 to 18; (CH₂)_nCOOH, where n is from 1 to 8; CY=CZCOOH, where Y and Z are independently selected from the group consisting of hydrogen, methyl, branched alkyl having from 1 to 20 carbon atoms and from one to three *cis* or *trans* double bonds; branched alkenyl having from 1 to 20 carbon atoms and having from one to three *cis* or *trans* double bonds; CY-CH₂, where Y is H, methyl, or phenyl; CH=CHY, where Y is C₆H₅; CH=CYCOOH, where Y is H or CH₃; (CH₂)₈CH=CH(CH₂)₈CH₃; or C₆H₍₂₋₆₎(COOH)₀₋₄, CH₂CH(COOH)CH₂-COOH;
w is 0.1-1.0;
x' is 0.1-1.9;
y is 0.1-1.9; and
n is 30-850.

(Specification, page 6, lines 24 to page 8, line 6).

The oxidized cellulose esters of the invention are soluble in aqueous alkaline solutions, water and/or common organic solvents. (Specification, page 5, lines 22-27). In comparison to previously made oxidized cellulose esters, the products of this invention offer a new class of biodegradable polymers that may be used as biomaterials and as drug carriers in medicine, pharmaceutics, agriculture, and veterinary fields. (Specification, page 5, line 29 to page 6, line 1). In addition, these compounds are less expensive to produce than some of the most commonly and widely used biodegradable polymers, such as poly(lactide-co-glycolide) copolymer. (Specification, page 6, lines 1-3).

No means plus function or set plus function elements are identified in the claim on appeal.

VII. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

A. Claim 36 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Lee et al. U.S. Patent No. 5,973,139.

VIII. ARGUMENT

A. Rejection Under 35 U.S.C. § 102(b), Anticipation by Lee et al., U.S. Patent No. 5,973,139.

Claim 36 was rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al., U.S. Patent No. 5,973,139. This rejection should be reversed.

1. The Law of Anticipation

Claimed subject matter is anticipated by the teachings of a reference only if the claimed subject matter is identically disclosed or described by the teachings of the reference. *Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913 (Fed. Cir.

1989)(“The identical invention must be shown in as complete detail as is contained in the patent claim.”) To be anticipated, the claimed subject matter must be disclosed “clearly and unequivocally” in the reference. *In re Arkley*, 455 F.2d 586, 587, 172 USPQ 524 (C.C.P.A. 1972)(“Thus, for the instant [anticipation] rejection… to have been proper, the …reference must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.”).

“It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it. Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.” *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1349, 64 USPQ2d 1202 (Fed. Cir. 2002). “Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Robertson*, 169 F.3d 743, 745, 20 USPQ2d 1749 (Fed. Cir. 1999). Applicant uses this standard to measure the rejection.

2. Lee Does Not Teach a Compound Having the Structure or Properties of the Claimed Invention, and Therefore Does Not Anticipate

In re-opening prosecution and giving a different anticipation rejection with Lee (5,973,139) as opposed to an earlier appealed anticipation rejection over Bogan (4,590,265), the Examiner has come full circle. The Office Action of July 24, 2003 the Examiner gave an anticipation rejection of claim 36 over Lee, and repeated it in the Final Rejection of March 9, 2004. In the meantime, Applicant prepared a Rule 132 Declaration that addressed both the Lee and Bogan references. In response to the Final Rejection of March 9, 2004, Applicant filed a RCE and the anticipation rejection over Lee (5,973,139) was dropped. Now, the Examiner returns to it! In so doing, he pours stale wine from an old open bottle. The

rejection now at issue was earlier dropped, in response to the arguments and affidavits of record.

In the rejection of October 2, 2008 that re-opened prosecution, the Examiner states that Lee discloses various carboxylated cellulose esters that include carboxylated cellulose acetate butyrate, carboxylated cellulose acetate propionate, carboxylated cellulose propionate butyrate and carboxylated cellulose acetate propionate butyrate (see col. 4, 4th par.), wherein the degree of substitution of each of the acetate, propionate, and butyrate groups along with the degree of substitution of the hydroxyl groups described for each of the recited compounds in col. 4, line 47 to col. 5, line 9 characterizes the carboxylated cellulose esters to a degree that anticipates the description of the oxidized cellulose esters represented in formula II of instance claim 36 when the R' and R" in formula II of instant claim 36 is represented as $(CH_2)_nCH_3$, where n is from 0 to 2. The symbols X, w, x', y' and n disclosed in formula II of claim 36 are also anticipated by the description of the carboxylated cellulose esters of the Lee patent. (See October 2, 2008 Office Action at P. 3). But disclosure to "a degree" is not anticipation!

A rejection under 35 U.S.C. § 102(b) for anticipation, such as made by the Examiner in the instant case, necessarily implies that the invention sought to be patented has been, "patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States," and therefore is not "new" - that there are no differences between what is claimed and what is disclosed in the prior art. Bearing this legal standard in mind, it is apparent that Lee does not specifically name, describe or claim any particular, individual compound anticipating Applicant's claims, nor is there any suggestion by Lee that any of its disclosed compounds are biodegradable (a claim limit), and therefore capable of being used for any of Applicant's intended purposes, for example, as a monolithic transparent film or biodegradable film coating. In fact, the evidence is that Lee is not biodegradable.

The Board's attention is directed to the evidence appendix of the Kumar Affidavits, Exhibits 1 and 2. Exhibit 2 addressed the previous anticipation rejection over Lee at

paragraphs 8, 14, 15 and 16. There it is pointed out that Lee is not biodegradable as evidenced by the low carboxylic content of its compounds (0.14-0.3% w/w) as well as the intended uses of the compounds. More specifically, the intended uses of the Lee compounds, similar to those of the now discarded Bogan et al. reference, include coating formulations for paper, plastic, metal, wood, chips and board, concrete brick, masonry brick, or galvanized sheets. The Lee compounds cannot be biodegradable if they are used for their intended described purpose. Thus, the evidence of the carboxylate content and the use in Lee both point to not meeting the biodegradable limitation. Of course, if it doesn't meet the limitation it cannot anticipate.

On page 3 of the October 2nd Office Action, the Examiner says that Lee, col. 4, lines 47-col. 5, line 9, "characterizes the carboxylated cellulose esters to a degree that anticipates (*emphasis added*) the description of the oxidized cellulose esters represented in formula II of instance claim 36 when the R' and R" in formulate II of instant claim 36 is represented as (CH₂)_nCH₃, where n is from 0 to 2." (See Office Action, page 3). It is not known what the Examiner means by characterizes...to a degree that anticipates.... The reality is that something either anticipates or does not. Here Applicant's argument is simple. There is no *prima facie* case of anticipation. The Examiner has not compared the limits of the claims element by element with the art and shown how the Lee reference provides them. There is no such thing as "anticipating to a degree". It either dos or it does not. Here it does not.

Even if it did "anticipate to a degree", Applicant has rebutted it with the Kumar Affidavit, Exhibit 2, which addresses why Lee does not make biodegradable oxidized cellulose polymers. It stands unrebutted by anything of record.

3. The Examiner Drew Unwarranted Conclusions from the Lee Reference

The Examiner's response to the argument concerning the biodegradability claim limitation, and the lack of biodegradability in the Lee reference is nonsensical. The Examiner argues that he is unpersuaded by Applicant's argument that the prior art discloses lactones. But the prior art referenced in the earlier brief as disclosing lactones, was the previously used

Bogan reference, not the current Lee. Lee fails for all the reasons mentioned in the previous brief section.

With regard to the Examiner's argument that Lee must anticipate the property (biodegradability) since if the prior art teaches the identical chemical structure Applicant discloses and/or claims the properties are necessarily present (citing *in re Spada*, 15 U.S.P.Q.2d 1655 (Fed. Cir. 1990) also fails), Applicant does not quarrel with *in re Spada*, but the problem is that the Examiner draws unwarranted conclusions from the Lee reference. Nothing in Lee teaches that it is the same compounds. Nothing in Lee teaches element by element identity. Nothing in Lee teaches biodegradability. And, no evidence of record rebuts the Kumar Affidavit of record indicating Lee is not biodegradable. The Supreme Court pointed out in *KSR Intern. Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007) rejections cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion. 127 S.Ct. 1727 at 1741. The Examiner has no appropriate reasoning to show how each element of so called class II compounds of claim 36 are met by Lee. Failing that, like all the other previous anticipation rejections, this one too should be dropped, and the case allowed.

IX. CONCLUSION

For the above-stated reasons, it is submitted that the claims are in a condition for allowability. The decision of the Examiner, therefore, should be reversed and the case allowed.

Please charge Deposit Account No. 26-0084 in the amount of \$270.00 to cover the required fee for the Appeal Brief. No other fees or extensions of time are believed to be due in connection with this Appeal Brief; however, please consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Respectfully submitted,



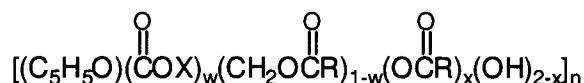
EDMUND J. SEASE, Reg. No. 24,741
McKEE, VOORHEES & SEASE
Attorneys of Record
CUSTOMER NO. 22885

801 Grand - Suite 3200
Des Moines, Iowa 50309-2721
515-288-3667

X. APPENDIX - CLAIMS

36. A biodegradable, oxidized cellulose ester having the following general formula I or II:

I.

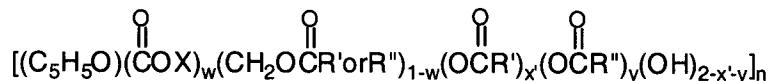


wherein:

X is selected from the group consisting of H, Na, K, Ca, NH₄, and NEt₃H;
whereby R is (CH₂)_nCOOH, where n is 2 to 4;
w is 0.1-1.0;
x is 0.1-2.0; and
n is 30-1500.

and

II.



wherein:

X is selected from the group consisting of H, Na, K, Ca, NH₄, and NEt₃H;
R' and R'' are each selected from the group consisting of: H; CF₃; (CH₂)_nCH₃, where n is from 0 to 18; (CH₂)_nCOOH, where n is from 1 to 8; CY=CZCOOH, where Y and Z are

independently selected from the group consisting of hydrogen, methyl, branched alkyl having from 1 to 20 carbon atoms and from one to three *cis* or *trans* double bonds; branched alkenyl having from 1 to 20 carbon atoms and having from one to three *cis* or *trans* double bonds; CY-CH₂, where Y is H, methyl, or phenyl; CH=CHY, where Y is C₆H₅; CH=CYCOOH, where Y is H or CH₃; (CH₂)₈CH=CH(CH₂)₈CH₃; or C₆H₍₂₋₆₎(COOH)₀₋₄, CH₂CH(COOH)CH₂-COOH;

w is 0.1-1.0;

x' is 0.1-1.9;

y is 0.1-1.9; and

n is 30-850.

XI. EVIDENCE APPENDIX

<u>Exhibit</u>	<u>Description</u>
1	Rule 132 Declaration of Dr. Vijay Kumar, entered in the record by the Examiner along with Appellants' October 24, . 2003 Amendment.
2	Supplemental Rule 132 Declaration of Dr. Vijay Kumar, entered in the record by the Examiner along with Appellant's December 10, 2004 Request for Continued Examination (RCE).

XII. RELATED PROCEEDINGS APPENDIX

None.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : KUMAR, Vijay
SERIAL NO : 10/007,866
FILED : December 6, 2001
TITLE : BIODEGRADABLE OXIDIZED CELLULOSE ESTERS

Grp./A.U. : 1623
Examiner : White, E.
Conf. No. : 6560
Docket No. : P04829US1

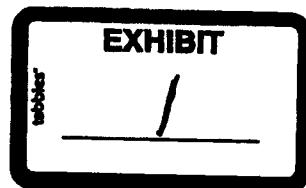
RULE 132 DECLARATION OF DR. VIJAY KUMAR

**Commissioner of Patents and Trademarks
Washington, D.C. 20231**

Dear Sir:

I, Dr. Vijay Kumar, hereby declare the following:

1. I am a co-inventor of the invention set forth in Serial No. 10/007,866.
2. I have obtained bachelor of science degrees in chemistry, zoology, and botany from Kanpur University in India. I received a master of science degree in chemistry from Lucknow University in 1972, and a Ph.D. degree in chemistry from Lucknow University in 1976, and another Ph.D. from Concordia University in Montreal in 1981. My postdoctoral work has been in the areas of pharmaceutics and chemistry.
3. From 1992-1996, I was a clinical assistant professor professor and from 1996-2002 an assistant professor in the pharmaceutics division of the College of Pharmacy, University of Iowa. From 2002 to present I have been an associate professor of the pharmaceutics in College of Pharmacy, University of Iowa.



4. I have conducted and supervised numerous pharmaceutical research projects since 1993. These projects have dealt primarily with pharmaceutical excipients and formulation techniques.

5. My current research has focused on carbohydrate polymers, especially cellulosic polymers, and their uses as pharmaceutical excipients, drug carriers, and biomaterials, biodegradable delivery systems, tissue engineering, interpolymer complexes, and drug-excipients.

6. I understand that the Examiner has rejected claims 1-12 under 35 U.S.C. 102(b) as being anticipated by Diamantoglou et al. (U.S. Pat. No. 5,008,385). The Examiner's contention that the cellulose derivatives of Diamantoglou anticipate the oxidized cellulose esters of the claimed invention is incorrect.

7. Diamantoglou discloses cellulose esters. Diamantoglou does not, however, disclose oxidized cellulose esters, as claimed in the present invention.

8. The polymers listed in the Diamantoglou patent describe cellulose derivatives containing carboxylic acid groups that are not derived from cellulose but introduced in cellulose as part of substituents. In other words, the carboxylic acid groups in cellulose derivatives are not directly linked to the cellulose backbone, but instead are linked to the side chains (or substituents). This is in contrast to the oxidized cellulose esters of the claimed invention whereby the carboxylic acid groups are an integral part of the oxidized cellulose, the starting material used to prepare the esters of the claimed invention. The carboxylic acid groups in the cellulose backbone (at carbon six position) results from an oxidation reaction.

9. Because the carboxylic acid groups are not directly linked to the cellulose backbone, the water-insoluble, fibrous, cellulose esters of Diamantoglou are not biodegradable, and therefore not useful for the purposes of the claimed invention, which include use as film-forming agents, drug carriers, and immobilizing matrix in the development of biodegradable controlled and/or sustained release pharmaceutical, agricultural, and veterinary compositions. In fact, the cellulose derivatives of Diamantoglou are used primarily as fibers and membranes in hemodialysis. (Col. 1, lines 8-10).

10. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Date: 10/23/03

Vijay Kumar

Dr. Vijay Kumar

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : KUMAR, Vijay
SERIAL NO : 10/007,866
FILED : December 6, 2001
TITLE : BIODEGRADABLE OXIDIZED CELLULOSE ESTERS

Grp./A.U. : 1623
Examiner : White, R.
Conf. No. : 6560
Docket No. : P04829US1

SUPPLEMENTAL RULE 132 DECLARATION OF DR. VIJAY KUMAR

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Sir:

I, Dr. Vijay Kumar, hereby declare the following:

1. I am a co-inventor of the invention set forth in Serial No. 10/007,866.
2. The present invention describes for the first time the synthesis of biodegradable oxidized cellulose esters.
3. In comparison to previously made oxidized cellulose esters, the products of this invention offer a new class of biodegradable polymers that undergo hydrolysis by enzymatic and/or chemical means *in vivo* and *in vitro*. They may therefore be used as biomaterials and as drug carriers in medicine, pharmaceuticals, agriculture, and veterinary fields.
4. In addition, these oxidized cellulose esters are less expensive to produce than some of the most commonly and widely used biodegradable polymers, such as poly(lactide-co-glycolide) copolymer.

Patent 500 record date



5. While others in the art have successfully synthesized carboxylated cellulose esters, such compounds are not biodegradable.

6. Studies show that the carboxyl content and degree of polymerization (DP) of oxidized cellulose play important roles in the degradation of oxidized cellulose *in vitro* and *in vivo*. In general, the higher the carboxyl content, or the lower the DP, the faster the rate of degradation of oxidized cellulose.

7. Compared to other biodegradable polymers, oxidized cellulose has received little consideration as a potential biomaterial or drug carrier. This is because it is practically insoluble in organic solvents and water, and hence, poses little or no formulation flexibility.

8. Recently, U.S. Patent No. 5,973,139 (Lee et al.) disclosed a process for producing carboxylated cellulose esters using oxidized cellulose materials containing about 0.14-0.3% w/w of carboxylic content. In this process, the starting cellulose source is first esterified and then hydrolyzed to give the product. The carboxylated cellulose esters prepared by this method are useful in the development of coating formulations that can be applied to paper, plastic, metal, wood, gypsum board, concrete brick, masonry or galvanized sheets.

9. Another previous method in the art for preparing carboxylated cellulose esters uses cellulose acetate butyrate as a starting material. The carboxylic groups are then introduced by treating the polymer with ozone. The disadvantage to the carboxylated cellulose esters prepared according to this method, however, is that they are not biodegradable.

10. The method referenced in paragraph 9 is exactly the method by which the carboxylated cellulose esters of Bogan et al. are prepared, i.e. cellulose acetate butyrate is reacted with ozone. Thus, the non-biodegradable cellulosic polymers of Bogan et al. are inherently different from that of the claimed invention.

11. The non-biodegradability of the polymers of Bogan et al. is also illustrated by the intended uses of their compositions. Specifically, the Bogan polymers are intended for use as pigment dispersions (Col. 17, line 44), metal coatings (Col. 18, line 34), ink compositions (Col. 20, line 51), and wood coatings (Col. 22, line 9). One skilled in the art

would realize that such products should not be biodegradable since they must remain intact in order to exhibit permanent sealing/protective qualities.

12. The oxidized cellulose esters of the claimed invention are further distinguished from those of Bogan et al. since they do not include lactone functional groups. Bogan et al. note that their carboxylated cellulose esters including the acetates, butyrates and propionates (termed "XAE") contain a lactone level of from about 4.52×10^{-5} to about 6.13×10^{-4} moles of lactone moiety per gram of XAE. In contrast, Applicants' oxidized cellulose esters do not include lactone moieties, as evidenced by the claimed structures.

13. The Bogan et al. compounds cannot be biodegradable if they are to be used for their intended purposes.

14. The compositions of Lee et al. also do not read on Applicants' claimed compounds since the Lee compounds are not biodegradable.

15. The non-biodegradability of the Lee et al. compounds is evidenced by the low carboxylic content of its compounds (0.14-0.3% w/w) as well as the intended uses of the compounds. More specifically, the intended uses of the Lee compounds, similar to those of Bogan et al., include coating formulations for paper, plastic, metal, wood, gypsum board, concrete brick, masonry or galvanized sheets.

16. The Lee et al. compounds cannot be biodegradable if they are to be used for their intended purposes.

17. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified

statement is directed.

Date: 7/6/04

Vijay Kumar
Dr. Vijay Kumar